510(k) Summary

K070935

Submitter: Sudimplant, SA
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NOV 0 9 2007

Contact: Mr. Didier Sailhan
Regulatory Affairs Manager
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Date: March 28, 2007

Device Name: T.B.R.® Zirconnect

Classification Name: Endosseous dental implant (21 CFR 872.3640) and Endosseous dental implant abutment (21 CFR 872.3630)

Device classification: Class II

Legally marketed device (predicate devices):
- 3i Osseotite Certain NT (K031475)
- T.B.R.® ide@ conic (K050956)

Description of the device:
The T.B.R.® Zirconnect dental implant system consists of root form, screw-type implants (made from Ti-6Al-4V) and restorative components with many options such as Ti-6Al-4V abutments, conical abutments, castable abutments and ball abutments. The system also includes surgical and laboratory accessories. Implants are double-packaged and provided sterile. Implants surface is roughened to promote osseointegration.

Intended use:
The T.B.R.® Zirconnect endosseous dental implant is a device intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

Performance:
This premarket notification was written in accordance with the FDA guidance "Class II Special controls guidance document:Root-form endosseous dental implants and endosseous dental abutments" issued on May 12, 2004. Test conclusions demonstrate the safety and effectiveness of T.B.R.® Zirconnect implant system.

Technological characteristics:

The overall design and characteristics of the T.B.R.® Zirconnect implants are similar to the predicated devices and as safe, as effective and as performs as well or better than the legally predicate devices.

	New device	Predicate Devices	
	T.B.R.® Zirconnect	**T.B.R.® Ide@ Conic**	***3i* Osseotite Certain NT**
510(k) number		K050956	K031475
Type	Self-Tapping Threaded Screw	Self-Tapping Threaded Screw	Self-Tapping Threaded Screw
Lengths (mm)	8-10.5-13-15,5	8-10.5-13-15,5	8,5-15
Diameters (mm)	3.5-4-5	3.5-4-5	3,25-6
Connection	Internal Octagon	Internal Octagon	Internal Hexagon
Shape	Tapered	Tapered	Tapered
Materials	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V
Surface	Sandblasted/ Acid-etched	Sandblasted/ Acid-etched	Acid-etched
Sterility	Gamma	Gamma	Gamma

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Didier Sailhan
Regulatory Affairs Manager
Sudimplant, SA
Parc De La Plaine
24 Impasse Rene Couzinet
31500 Toulouse,
FRANCE

Re: K070935
Trade/Device Name: T.B.R.® Zirconnect
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: October 19, 2007
Received: October 22, 2007

Dear Mr. Sailhan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D. for
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070935

Device Name: T.B.R.® Zirconnect

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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